

# **Notice of Allowability**

**Application No.**

09/617,116

**Applicant(s)**

AGHI ET AL.

**Examiner**

Quang Nguyen, Ph.D.

**Art Unit**

1636

## **-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/22/03 and 1/2/04.
2. ☒ The allowed claim(s) is/are 14-32,34 and 36.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## **Attachment(s)**

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| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>3/5/04</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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### EXAMINER'S AMENDMENT

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/02/04 has been entered.

Applicants' amendment filed on 12/22/03 has been entered.

Amended claims 14-32, 34 and 36 are pending in the present application.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Karen R. Markowicz on March 05, 2004.

The application has been amended as follows:

**In the Claims:** Claims 14, 25-26 and 32 have been amended as follows:

**Claim 14:** A method of enhancing the cytotoxic sensitivity of neoplastic cells to an antifolate drug, said neoplastic cells expressing an endogenous level of folypolyglutamyl synthetase (FPGS), said method comprising:

(a) delivering directly to said neoplastic cells a vector, said vector comprising a DNA sequence encoding [folypolyglutamyl synthetase (FPGS)], operably linked to a

promoter, wherein said FPGS is expressed in said neoplastic cells at a level higher than the endogenous FPGS level of said neoplastic cells;

(b) treating the neoplastic cells in step (a) with an antifolate drug that is polyglumated by [said] FPGS; and

(c) enhancing the cytotoxic sensitivity of said neoplastic cells to said antifolate drug.

**Claim 25:** The method of claim 22, wherein said viral vector is [derived from] a retrovirus, adenovirus, adeno-associated virus, herpes virus, poliovirus, papillomavirus, or lentivirus.

**Claim 26:** The method of claim 25, wherein said viral vector is [derived from] a retrovirus, adenovirus, or herpes virus.

**Claim 32:** A method of enhancing the cytotoxic sensitivity of neoplastic cells to methotrexate or edatrexate, said neoplastic cells expressing an endogenous level of folypolyglutamyl synthetase (FPGS), said method comprising:

(a) delivering directly to said neoplastic cells a vector, said vector comprising a DNA sequence encoding [folypolyglutamyl synthetase (]FPGS[)], operably linked to a promoter, wherein said FPGS is expressed in said neoplastic cells at a level higher than the endogenous FPGS level of said neoplastic cells;

(b) treating the neoplastic cells in step (a) with methotrexate or edatrexate; and

(c) enhancing the cytotoxic sensitivity of said neoplastic cells to said methotrexate or edatrexate.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.**

*Quang Nguyen, Ph.D.*

  
DAVID GUZO  
PRIMARY EXAMINER